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II 510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

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PRODUCT NAME: Formulation Preparation Device

CLASSIFICATION NAME: General Hospital Devices
Class II, 80 LHI, I.V. Fluid Transfer Set

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K792227	Multi-Ad Fluid Dispensing System	National Patent Development Corporation

DEVICE DESCRIPTION:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce the Formulation Prepration Device. The Formulation Device is used for preparing and dispensing medications from rubber stoppered vials.

MATERIAL:

The Formulation Preparation Device is composed of materials that have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

SUBSTANTIAL EQUIVALENCE:

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The Formulation Preparation Device is equivalent in materials, form, and intended use to the Multi-Ad Fluid Dispensing System currently marketed by B. Braun Medical formerly National Patent Development. There are no new issues of safety or effectiveness raised by the Formulation Preparation Device.

SAFETY AND EFFECTIVENESS:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.